

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

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Altana Pharma AG and Wyeth

ALTANA PHARMA AG and
WYETH,

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES,
LTD. and SUN PHARMACEUTICAL
ADVANCED RESEARCH CENTRE, LTD.

Defendants.

CIVIL ACTION NO.
05-3920 (JLL)

**REPLY TO SUN PHARMACEUTICAL INDUSTRIES, LTD.
AND SUN PHARMACEUTICAL ADVANCED
RESEARCH CENTRE, LTD.'S COUNTERCLAIMS**

Plaintiffs Altana Pharma AG and Wyeth (“Plaintiffs”) hereby reply to the counterclaims of defendants Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Advanced Research Centre, Ltd. (“Sun”) as follows:

1. Plaintiffs admit the allegations of paragraph 1.
2. Plaintiffs admit the allegations of paragraph 2.
3. Plaintiffs admit the allegations of paragraph 3.
4. Plaintiffs admit that this is a declaratory judgment action under 28 U.S.C.

§§ 2201 and 2202. Plaintiffs admit that the counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and under the Food, Drug and Cosmetic Act of the United States, 21 U.S.C. § 355(j). Plaintiffs further admit that jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 21 U.S.C. 355(j) as to the ‘579 patent.

Plaintiffs deny that jurisdiction is proper as to the ‘881 patent, and further deny the remaining allegations of paragraph 4.

5. Plaintiffs admit the allegations of paragraph 5.
6. Plaintiffs admit the allegations of paragraph 6.
7. Plaintiffs admit that Altana is currently the owner of the United States

Letters Patent No. 4,758,579 (“the ‘579 patent”), which claims, *inter alia*, pantoprazole sodium, and the United States Letters Patent No. 6,780,881 (“the ‘881 patent”) which claims, *inter alia*, freeze-dried pantoprazole preparation and injection. Plaintiffs admit that what appears to be a copy of the ‘881 patent is attached as Exhibit A to Sun’s Answer, Affirmative Defenses, and Counterclaims. Plaintiffs deny the remaining allegations of paragraph 7.

8. Plaintiffs admit that Wyeth Pharmaceuticals, Inc. is a wholly-owned subsidiary of Wyeth, and holds an approved New Drug Application from the FDA for pantoprazole sodium for injection. Plaintiffs further admit that under the terms of Altana's licensing agreement with Wyeth, Altana granted Wyeth an exclusive license to distribute pantoprazole in the U.S. market. Plaintiffs deny the remaining allegations of paragraph 8.

9. Plaintiffs admit that Sun sent a notice to Plaintiffs in which Sun represented that it filed an ANDA for pantoprazole sodium for injection. Plaintiffs deny each other allegation of paragraph 9.

10. Plaintiffs admit that Altana received notice of the Sun certification on or about June 30, 2005, and Wyeth received notice of the Sun certification by July 11, 2005. Plaintiffs deny each other allegation of paragraph 10.

11. Plaintiffs admit Sun's notice letter dated June 25, 2005, contained a section entitled Offer of Confidential Access to Application, and that Sun provided ANDA No. 77-674 to Plaintiffs pursuant to a Confidentiality Agreement. Plaintiffs deny the remaining allegations of paragraph 11.

12. Plaintiffs admit that Plaintiffs filed the present action on August 5, 2005, alleging, *inter alia*, infringement and willful infringement of the '579 patent. Plaintiffs also admit that the complaint contains no allegations of infringement of the '881 patent. Plaintiffs deny each other allegation of paragraph 12.

13. Plaintiffs admit that there is an actual, substantial and continuing justifiable controversy between Plaintiffs and Sun concerning the infringement, validity and enforceability of the '579 patent. Plaintiffs deny each other allegation of paragraph 13.

14. Plaintiffs reallege each reply to each allegation of paragraphs 1-13 as if set forth specifically here verbatim.

15. Plaintiffs deny the allegations of paragraph 15.

16. Plaintiffs deny the allegations of paragraph 16.

17. Plaintiffs reallege each reply to each allegation of paragraphs 1-13 as if set forth specifically here verbatim.

18. Plaintiffs deny the allegations of paragraph 18.

19. The allegations of paragraphs 19-22, and Counts III and IV of Sun's Counterclaims, are the subject of a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1), thus no responsive pleading is required.

20. Responding to Sun's requested relief, Plaintiffs deny that Sun is entitled to any relief whatsoever, whether as requested or otherwise.

Respectfully submitted,

Dated: October 31, 2005

s/Andrew T. Berry (AB-4170)

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